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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,997	10/04/2005	Kai Schiemann	MERCK-3071	6470
23599 7590 08/30/2010 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
MURRAY, JEFFREY H				
ART UNIT		PAPER NUMBER		
1624				
NOTIFICATION DATE		DELIVERY MODE		
08/30/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary

Application No.

10/551,997

Applicant(s)

SCHIEMANN ET AL.

Examiner

JEFFREY H. MURRAY

Art Unit

1624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15, 17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 13, 15, 20 and 21 is/are allowed.
- 6) ☒ Claim(s) 17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to an amendment filed on July 22, 2010. The final action dated February 25, 2010 is being withdrawn, and this non-final action will replace it. There are seventeen claims pending and seventeen claims under consideration. Claims 12, 14, 16 and 18 have been cancelled. The application relates generally to chromenoneindole derivatives of the Formula I and finding novel compounds which have high bioavailability and are capable of significantly increasing the serotonin level in the brain.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any of the errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating depression, does not reasonably provide enablement for all of the other diseases listed within the broad Claim 17. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation. (*United States v. Teletronics Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988)).

Claims 17 and 19 define a method to treating several different diseases in a patient in need thereof. The diseases and disorders listed in claim 17 covers an array of diseases which are largely unrelated and have different modes of action and different origins. The term covers several diverse disorders such as Alzheimer's Disease; extrapyramidal motor side effects of neuroleptics and of Parkinson's Disease and amyotrophic lateral sclerosis (ALS).

These diseases exhibit a very broad range of effects and origins. For example, some give progressive dementia without other prominent neurological signs, such as Alzheimer's Disease, whereas other dementias do have such signs. Many give distinctive and different patterns of effect, yet can leave visuospatial skills and day-to-day memorizing largely unaffected. Some of these diseases give muscular wasting without sensory changes such as ALS.

The toxic protein, for those diseases that involve one, also varies. In some cases it is tau, i.e. in Alzheimer's Disease. Alzheimer's Disease also involves β -amyloid. For Parkinson's disease it is α -synuclein. The nature of the protein deposits, when these

occur, varies as well. In Alzheimer's Disease, there are extracellular plaques from β -amyloid and neurofibrillary tangles (from tau). In Parkinson's disease it is Lewy bodies and in ALS it is Bunina bodies. Also note that the disease form is not necessarily related to the protein deposits. For example, Alzheimer's Disease gives progressive dementia without other prominent neurological signs.

The disease genes vary considerably as well. In Alzheimer's Disease, there is toxic gain of function with APP and loss of function of Presenilin 1 and Presenilin 2. With Parkinson's disease, there is toxic gain of function with α -synuclein, and loss of function of Parkin and UCHL1. In ALS there is toxic gain of function with SOD1.

As can be seen from the above, these diseases do not have any type of common origin or mode of action. There is no art recognized assay presently available in predicting whether a given compound would be able to treat these "very-difficult-to-treat diseases." Some diseases affect the mind, some affect movement, some affect both, and some effect neither. For example, Alzheimer's Disease is the most common neurodegenerative disorder. However, its etiology involves both tau protein and β -amyloid. Such a statement is not true for any other important disorder, and indeed some of the other disorders involve neither one of those. No new matter is permitted. Appropriate correction is required.

Allowable Subject Matter

Claims 1-11, 13, 15, 20 and 21 are allowed.

Claims 1-11, 13, 15, 20 and 21 are free of the prior art. No prior art was seen in which contains compounds of Formula I as seen in Claim 1 of the current application.

Conclusion

Claims 17 and 19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/
Patent Examiner , Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624